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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,307	03/10/2004	Michele Cargill	CL001509	9084

25748 7590 07/24/2006

CELERA GENOMICS
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EXAMINER	
SHAW, AMANDA MARIE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,307	CARGILL ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, and 21-22 drawn to methods for identifying an individual who has an altered risk for developing myocardial infarction using a SNP, classified in class 435, subclass 6.

II. Claims 7-9, 13-20 drawn to nucleic acids, classified in class 536, subclass 23.1.

III. Claims 10, drawn to polypeptides, classified in class 530, subclass 350.

IV. Claims 11-12, drawn to antibodies, classified in class 424, subclass 130.1.

V. Claims 23, drawn to methods for detecting a variant polypeptide, classified in class 435, subclass 7.1.

VI. Claim 24, drawn to methods of identifying an agent classified in class 514, subclass 2.

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid may be

used in a materially different method such as purification and isolation, aptamer screening methods, compound screening methods or antisense methods.

Inventions I and III and I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention III and the antibodies of invention IV are not disclosed as capable of use in the method of invention I. The method of invention I requires detecting a single nucleotide polymorphism in a nucleic acid sequence.

Inventions I and V and I and VI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention do not overlap in scope, the inventions are not obvious variants and the inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention I requires detecting a single nucleotide polymorphism in a nucleic acid sequence. The method of invention V requires contacting a reagent with a variant polypeptide and detecting the binding. The method of invention VI requires contacting a polypeptide with a candidate agent in order to identify an agent useful for treating myocardial infarctions.

Inventions II and III are patentably distinct in structure and physicochemical properties. Invention II is drawn to nucleic acids whereas invention III is drawn to polypeptides. Nucleic acids are composed of nucleotides and polypeptides are composed of amino acids. Accordingly, these compounds are independent and distinct from one another due to their diverse chemical structure, their expected different chemical properties, modes of action, different effects and reactive conditions. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention III do not require the particular products of the nucleic acids of invention II since the proteins of invention III can be isolated from natural sources or chemically synthesized.

Inventions II and IV are patentably distinct in structural and functional properties. Invention II is drawn to nucleic acids, while Invention IV is drawn to antibodies. Nucleic acids are composed of nucleotides and antibodies are composed of amino acids. Accordingly, these compounds are independent and distinct from one another due to their diverse chemical structure, their expected different chemical properties, modes of action, different effects and reactive conditions. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while antibodies may be utilized in ligand binding assays or immunotherapies.

Inventions II and V and II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the nucleic acids of Invention II are not disclosed as capable of use in the methods of inventions V and VI. The method of invention V requires contacting a reagent with a variant polypeptide and detecting the binding. The method of invention VI requires contacting a polypeptide with a candidate agent in order to identify an agent useful for treating myocardial infarctions.

Inventions III and IV are patentably distinct in structural and functional properties. Invention III is drawn to polypeptides, while Invention IV is drawn to antibodies. Although both proteins and antibodies are composed of amino acids, the antibodies of Invention IV have distinct structural limitations not required of the polypeptides of Invention III. Furthermore, antibodies have particular immunological functions that distinguish them from other polypeptides.

Inventions III and V and III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product. The product as claimed is a polypeptide which can also be used to generate antibodies.

Inventions IV and V and IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Invention IV is not disclosed as

capable of use in the methods of inventions V and VI. The method of invention V requires contacting a reagent with a variant polypeptide and detecting the binding. The method of invention VI requires contacting a polypeptide with a candidate agent in order to identify an agent useful for treating myocardial infarctions.

Inventions V and VI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention do not overlap in scope, the inventions are not obvious variants and the inventions are drawn to materially different method, which have different process steps and different objectives. The method of invention V requires contacting a reagent with a variant polypeptide and detecting the binding. The method of invention VI requires contacting a polypeptide with a candidate agent in order to identify an agent useful for treating myocardial infarctions.

3. The claims read on patentably distinct inventions drawn to multiple nucleic acid and amino acid sequences. The claims encompass nucleic acid sequences selected from the group of sequences consisting of SEQ ID NO: 1-450 and 901-43787. Each nucleic acid sequence, has a different melting temperature, a different specificity of hybridization, and encodes for a protein having a different biological activity. For example, a nucleic acid sequence comprising SEQ ID NO: 1 is chemically, structurally

and functionally distinct from a nucleic acid comprising SEQ ID NO: 8. A search for a nucleic acid sequence comprising SEQ ID NO: 1 would not be co-extensive with a search for a nucleic acid sequence comprising SEQ ID NO: 8. Further, a finding that nucleic acid sequence comprising SEQ ID NO: 1, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that a nucleic acid sequence comprising SEQ ID NO: 8 is also novel and unobvious over the prior art. Similarly, a finding that a nucleic acid sequence comprising SEQ ID NO: 1 is anticipated or obvious over the prior art would not necessarily extend to a finding that a nucleic acid sequence comprising SEQ ID NO: 8 is also anticipated or obvious over the prior art.

The claims also encompass amino acid sequences 451-900. Each amino acid sequence, has a different melting temperature, a different specificity of hybridization, and encodes for a protein having a different biological activity. For example, an amino acid sequence comprising SEQ ID NO: 451is chemically, structurally and functionally distinct from a nucleic acid comprising SEQ ID NO: 899. A search for an amino acid sequence comprising SEQ ID NO: 451 would not be co-extensive with a search for an amino acid sequence comprising SEQ ID NO: 899. Further, a finding that amino acid sequence comprising SEQ ID NO: 451, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that a amino acid sequence comprising SEQ ID NO: 899 is also novel and unobvious over the prior art. Similarly, a finding that an amino acid sequence comprising SEQ ID NO: 451 is anticipated or obvious over the prior art would not necessarily extend to a finding that an amino acid sequence comprising SEQ ID NO: 899 is also anticipated or obvious over the prior art.

Accordingly, the nucleic acid and amino acid sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, if the applicant elects an invention drawn to nucleic acids, then the applicant should elect one sequence selected from the group consisting of SEQ ID NO: 1-450 and 901-43787. Should the applicant elect a sequence drawn to amino acids, then the applicant should elect one sequence selected from the group consisting of SEQ ID NO: 451-900.

Applicant is further required to distinctly point out the location in the drawings, figures, or SEQ IDS of the instant application to which the elected sequence is drawn. Please include in the selection of a sequence or specific combination of sequence the SEQ ID(s), the Genebank numbers) (or any other identifier), the table or figure number, and the row or column location in the table.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-VI require different searches that are not co-extensive. For instance, a literature search for the methods of inventions I, V, and VI is not co-extensive with a literature search for the products of inventions II, III, or VI. For instance, a finding that, for example, the method of invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of

inventions V or VI or the products of inventions II, III, or IV were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of inventions V or VI or the products of inventions II, III, or IV are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

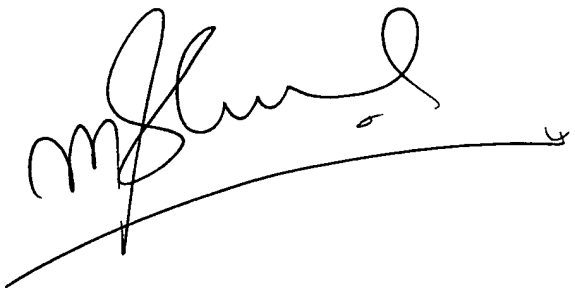
7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final

rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER